

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCA41062-YUH	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/KR2004/002646	International filing date(day/month/year) 15 OCTOBER 2004 (15.10.2004)	Priority date (day/month/year) 16 OCTOBER 2003 (16.10.2003)
International Patent Classification (IPC) or national classification and IPC IPC7 C07D 403/06		
Applicant YUHAN CORPORATION et al		



1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 07 JULY 2005 (07.07.2005)	Date of completion of this report 12 SEPTEMBER 2005 (12.09.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, Mi Jeong Telephone No. 82-42-481-5601 

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/002646

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1 - 10	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are referred to in this report:

D1: CN 1113913 A (27 Dec. 1995)

D2: CN 1110970 A (01 Nov. 1995)

D3: US 6388091 B1 (14 May 2002)

1. Novelty and Inventive Step

Claims 1-10 of the present invention relate to a process for preparing a compound of formula 1 (1,2,3,9 -tetrahydro -9- methyl -3 [(2-methyl -1H -imidazole-1-yl) methyl]-4H-carbazol-4-one, i.e. ondansetron), which comprises reacting a compound of formula 2 with a compound of formula 3 and a compound of formula 4 by one step in the presence of an acid, an alkylsilylhalide compound or an acylhalide compound in a solvent.

D1 discloses that 2-methyl imidazole salt, N-methyl tetrahydrocarbazolone, and polyformaldehyde are reacted to synthesize ondansetron by one step.

D2 discloses a process for preparing ondansetron by reacting a compound of formula(II), aldehyde, and 2-methyl imidazole.

D3 discloses a process for preparing ondansetron by reacting a compound of formula(II) and a compound of formula (III) in the presence of a halosilane compound.

As mentioned before, D1-D3 disclose a process for preparing ondansetron, but none of D1-D3 discloses a process using the reactant compound of formula 2 in the present invention. Thus, claims 1-10 of the present invention can be considered to be novel over D1-D3 [Article 33(2) PCT].

Since there is no suggestion or implication in D1-D3 to lead those who skilled in the art to expect that the said three reactants(formula 2, 3, 4) in the present invention can be reacted to prepare ondansetron by one step, the inventive step of claims 1-10 in the present invention can be acknowledged over D1-D3 [Article 33(3) PCT].

2. Industrial Applicability

The subject-matter of claims 1-10 appears to be industrially applicable [Article 33(4) PCT].